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FDA/CDRH Webinar

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Use of Symbols in Medical Device Labeling Final Rule

Presented by:

Antoinette (Tosia) Hazlett, MSN, RN
Scott Colburn CAPT, USPHS
Office of the Center Director
Center for Devices and Radiological Health

July 25, 2016

Agenda

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- **Options for the Use of Symbols**
- **Definition of a Symbols Glossary**
- **Consensus Standards**
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- **Federal Register Notice Standards Recognition List #42**
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- **Declarations of Conformity**
- **Standards Recognition List**

Purpose of the Webinar

The purpose of this webinar is to help industry and patient groups learn more about this final rule and the new standards recognition notice.

Background

- On April 19, 2013, the FDA published a proposed rule to revise certain medical device and biological product labeling regulations by explicitly allowing labeling to contain certain stand-alone symbols (symbols without adjacent text).
- The FDA currently recognizes a list of standards that contain a limited number of stand-alone symbols.
- The medical device industry has requested the ability to use stand-alone symbols on domestic device labeling, consistent with their current use on devices manufactured for European and other foreign markets.

Purpose of the Regulatory Action

- Permit the use of stand-alone symbols in medical device labeling without adjacent explanatory text if certain requirements are met
- Harmonize the U.S. device labeling requirements with international regulatory requirements
- To make labeling more user-friendly by replacing text that may be small and difficult to read with symbols
- Potentially reduce costs associated with designing and redesigning labeling for medical devices currently marketed in the U.S., the EU and other foreign markets.

Scope

- Manufacturers may use standardized symbols without adjacent explanatory text ("stand-alone symbols") as allowed by the final rule, but may also opt to use symbols accompanied by adjacent explanatory text or no symbols at all.

- A symbols glossary is required to be included in the labeling, but may be provided in paper or electronic format.

- The final rule explicitly permits the use of stand-alone symbols in the labeling for all medical devices, regardless of the user of the device, as long as certain requirements are met.

- Additionally, the final rule allows the use of the symbol statement "Rx Only" for labeling of prescription devices.

Options for the Use of Symbols

There are basically three options with respect to symbols in device labeling under the final rule:

- no use of symbols,
- use of symbols with explanatory text, or
- use of stand-alone symbols from a Standards Development Organization (SDO) standard with a symbols glossary.

Definition of a Symbols Glossary

A symbols glossary is a compiled listing of:

(1) each SDO-established symbol used in the labeling for the device;

(2) the title and the designation number of the SDO-developed standard containing the symbol;

(3) the title of the symbol and its reference number, if any, in the standard; and,

(4) the meaning or explanatory text of the symbol as provided in the FDA recognition or, if the symbol is not in an FDA-recognized standard or is not used according to the specifications for use of the symbol set out in the FDA-recognized standard, the explanatory text as provided in the standard.

Symbols Glossary

- The symbols glossary may be in a paper or electronic format as long as it is included in the labeling for the device. The labeling on or within the package containing the device must bear a prominent and conspicuous statement identifying the location of the symbols glossary.

- The final rule permits the device package labeling on or within the package to refer to a symbols glossary available electronically -- displayed, for example on the manufacturer's website -- to reduce production and shipping burdens for printed glossaries.

FDA Recognized Consensus Standards Containing Symbols

From the rule …

Symbols established in a standard developed by a standards development organization (SDO) may be used in medical device labeling without adjacent explanatory text.

Consensus Standards

What is a consensus standard?

- **Technical documents that outline important criteria about specific topics**
  - e.g., manufacturing specifications, test methods, guidelines, practices, labeling etc…
- **Developed by stakeholders through consensus principles under the leadership of SDOs**
  - e.g., AAMI, CLSI, ASQ, ADA, ISO, IEC, ASTM Int.

How Standards Are Used

- **Stakeholders heavily utilize standards in the development of medical devices for all aspects of their operations**
- **CDRH utilizes standards throughout the Center**
  - premarket, postmarket, compliance, research, quality systems
- **CDRH determines which standards we will "recognize" for regulatory needs to support its mission**
- **CDRH can withdraw recognition of all or part of a standard that is:**
  - out-of-date
  - no longer published
  - no longer appropriate to support public health or regulatory needs
    - could conflict with existing policy, guidance, regulations

21 USC Section 514(c)

(c) Recognition of standard

(1)(A)…"by publication in the FR, recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a premarket requirement or other applicable requirement under this chapter to which such standard is applicable"

21 USC 514(c) – cont'd

(1)(B) If a person elects to use a standard recognized by the Secretary under subparagraph (A) to meet the requirements described in such subparagraph, the person shall provide a declaration of conformity to the Secretary that certifies that the device is in conformity with such standard. A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to meet any requirement regarding devices under this chapter.

21 USC 514(c) – cont'd

(2) The Secretary may withdraw such recognition of a standard through publication of a notice in the Federal Register if the Secretary determines that the standard is no longer appropriate for meeting a requirement regarding devices under this chapter.

21 USC Section 514(c) – cont'd

(3)(A) Subject to subparagraph (B), the Secretary shall accept a declaration of conformity that a device is in conformity with a standard recognized under paragraph (1) unless the Secretary finds—

- (i) that the data or information submitted to support such declaration does not demonstrate that the device is in conformity with the standard identified in the declaration of conformity; or
- (ii) that the standard identified in the declaration of conformity is not applicable to the particular device under review.

Federal Registration Notice Standards Recognition List #42 – Symbols

- https://federalregister.gov/a/2016-13990

List 42 specific to standards recognized to support the Use of Symbols in Medical Device Labeling Final Rule.

Updates relevant currently recognized standards and three new international standards.

CDRH's Recognized Consensus Standards database can be found at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

Declarations of Conformity

- **Can be submitted by a sponsor to certify that a device conforms to applicable requirements of an [FDA] recognized consensus standard**

- **Can reduce the amount of supporting data and information that is needed**
  - submitters may need to explain why the standard is applicable to the device & how it conforms to the standard

Standards Recognition List

Updates to currently recognized standards

ISO & ANSI/AAMI/ISO 27185
Symbols to be used with cardiac rhythm management device labels

ISO & ANSI/AAMI/ISO 15223-1
Medical devices—Symbols to be used with medical devices labels - General requirements

ASTM F2503-13
Standard Practice For Marking Medical Devices And Other Items For Safety In The Magnetic Resonance Environment

New recognitions

IEC 60417:2002 DB
Graphical symbols for use on equipment

ISO 7000: Fifth edition 2014/01/15
Graphical symbols for use on equipment – Registered symbols

IEC/TR 60878 Ed. 3.0 b:2015
Graphical symbols for electrical equipment in medical practice

Questions?

Division of Industry and Consumer Education:
DICE@fda.hhs.gov

Slide Presentation, Transcript and Webinar Recording will be available at:

http://www.fda.gov/training/cdrhlearn

Under Heading “Specialty Technical Topics”, in the section titled “Labeling"